510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92 and the Safe Medical Device Act of 1990.

The assigned 510(k) Number is: K132249

1. Date Prepared

August 8, 2013

2. Applicant Information

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SEP 13 2013

3. Regulatory Information

Table 1. Regulatory Information for ADVIA Centaur FT4 and T4 Assays

	FT4	T4
Trade Name	ADVIA Centaur® FT4	ADVIA Centaur® T4
Model Numbers	06490106 (5-pack) 06490092 (1-pack)	09236439 (5-pack) 08074354 (1-pack)
Common Name	Radioimmunoassay, free thyroxine	Enzyme immunoassay, non-radiolabeled, total thyroxine
Classification Name	Free thyroxine test system	Total thyroxine test system
FDA Classification	Class II	Class II
Review Panel	Clinical Chemistry	Clinical Chemistry
Product Code	CEC	KLI
Regulation Number	862.1695	862.1700

4. Predicate Device Information

The inclusion of pediatric reference intervals to the labeling (Package Inserts) of the ADVIA Centaur FT4 and T4 assays does not require any other device modifications (i.e. no change to design or manufacturing process). Therefore, as shown in the table below, the predicate and subject devices are the same.

Table 2. Summary of Predicate Devices for ADVIA Centaur FT4 and T4 Assays

	FT4	T4
Predicate Device	ADVIA Centaur® FT4	ADVIA Centaur® T4
Subject Device	Same (As above)	Same (As above)
Original 510(k)	K080167	K905532

5. Substantial Equivalence Information

The following table demonstrates substantial equivalence between the predicate ADVIA Centaur thyroid assays (with unmodified labeling) and ADVIA Centaur thyroid assays which have modified Instructions for Use (Package Inserts) including pediatric reference intervals.

Table 3. Summary of Substantial Equivalence for ADVIA Centaur Thyroid Assays

Item	Predicate Device (Unmodified Labeling)	Subject Device (With Pediatric Reference Intervals)
Analytes	free thyroxine (FT_4) total thyroxine (T_4)	Same
Reagents	ADVIA Centaur FT4 ADVIA Centaur T4	Same
Instruments	ADVIA Centaur ADVIA Centaur XP	Same
Intended Use Statements	ADVIA Centaur FT4 For *in vitro* diagnostic use in the quantitative determination of free thyroxine (FT_4) in serum or plasma (heparinized or EDTA), using the ADVIA Centaur and ADVIA Centaur XP systems. Measurements of free thyroxine are used in the diagnosis and treatment of thyroid disease. ADVIA Centaur T4 For *in vitro* diagnostic use in the quantitative determination of thyroxine (T_4) in serum using the ADVIA Centaur and ADVIA Centaur XP systems.	ADVIA Centaur FT4 Same ADVIA Centaur T4 For *in vitro* diagnostic use in the quantitative determination of thyroxine (T_4) in serum using the ADVIA Centaur and ADVIA Centaur XP systems. Measurements of thyroxine are used in the diagnosis and treatment of thyroid disease.
Analytical Measuring Range (Assay Range)	ADVIA Centaur FT4 0.1 – 12 ng/dL (1.3 – 155 pmol/L) ADVIA Centaur T4 0.3 – 30 µg/dL (3.9 – 387 nmol/L)	ADVIA Centaur FT4 Same ADVIA Centaur T4 Same
Adult Reference Intervals	ADVIA Centaur FT4 Euthyroid, Hypothyroid, Hyperthyroid ADVIA Centaur T4 Apparently Healthy Individuals, Hypothyroid, Hyperthyroid, Pregnant Euthyroid, Sick Euthyroid	ADVIA Centaur FT4 Same ADVIA Centaur T4 Same
Pediatric Reference Intervals	None	Infants (01 – 23 months) Children (02 – 12 years) Adolescents (13 – 21 years)

6. Standard/Guidance Document Reference

Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline -- Third Edition (CLSI C28-A3c).

7. Pediatric Reference Intervals

Data from a total of 454 patients (72 infants, 190 children, 129 adolescents) were analyzed to establish the ADVIA Centaur thyroid assay reference intervals for the studied pediatric population. These pediatric reference intervals, as well as the previously-established euthyroid adult reference intervals and analytical measuring ranges, are presented below.

Table 4. Comparison of Pediatric and Adult 95% Reference Intervals

	FT4	T4
Infants (01 – 23M)	0.94 – 1.44 ng/dL	6.03 – 13.18 µg/dL
Children (02 – 12Y)	0.86 – 1.40 ng/dL	5.50 – 12.10 µg/dL
Adolescents (13 – 21Y)	0.83 – 1.43 ng/dL	5.50 – 11.10 µg/dL
Euthyroid Adults*	0.89 – 1.76 ng/dL	4.50 – 10.90 µg/dL
Assay Range*	0.10 – 12.0 ng/dL	0.30 – 30.00 µg/dL

* Information taken from existing Instructions for Use (Package Inserts)

8. Performance Characteristics

The inclusion of pediatric reference intervals in the Instructions for Use (Package Inserts) does not necessitate the collection of additional analytical performance data. Therefore, all analytical performance data previously reviewed for the ADVIA Centaur FT4 and T4 assays continues to apply to these assays. All performance data is cross-referenced to the original 510(k) submissions for the FT4 and T4 assays (K905532 and K080167) and subsequent submissions demonstrating performance of the assays on the ADVIA Centaur system (K971418).

Specifically, the following studies are not needed for the purpose of this submission:

- Precision/Reproducibility
- Linearity
- Calibrator/Assay Traceability
- Calibrator/Assay Stability
- Assay Cut-off
- Method Comparison
- Matrix Comparison
- Sensitivity (Detection Limits, LoB, LoD, LoQ)
- Analytical Specificity

9. Shelf-Life

The inclusion of pediatric reference intervals in the Instructions for Use (Package Inserts) does not necessitate the collection of additional stability data. Therefore, all stability methods, acceptance criteria and data previously reviewed for the ADVIA Centaur FT4 and T4 assays continues to apply to these assays. All stability information is cross-referenced to the original 510(k) submissions for the FT4 and T4 assays (K905532 and K080167) and subsequent submissions demonstrating performance of the assays on the ADVIA Centaur system (K971418).

Specifically, the following stability studies are not needed for the purpose of this submission:

- Shelf Life Stability
- Onboard Stability
- Open Vial Stability

10. Conclusions

The ADVIA Centaur FT4 and T4 assays with pediatric reference intervals are substantially equivalent to the currently marketed ADVIA Centaur FT4 and T4 assays.

The inclusion of pediatric reference intervals in the Instructions for Use (Package Inserts) does not require a change in the device design or a change in the manufacturing process.

All performance data is cross-referenced to the original 510(k) submissions for these assays (K905532 and K080167) and subsequent submissions demonstrating performance of the assays on the ADVIA Centaur system (K971418).

The addition of pediatric reference intervals for the ADVIA Centaur thyroid assays is further supported by the following rationale:

1. Testing of pediatric patients is within the established indications for use (i.e. for use in the diagnosis and treatment of thyroid disease), as described in 21 CFR §862.1695 and 21 CFR §862.1700.
2. The newly-established pediatric reference intervals are either within or are above the previously-established reference intervals for euthyroid (normal thyroid) adult populations and they are within the analytical measuring ranges of the ADVIA Centaur FT4 and T4 assays. Therefore, the ADVIA Centaur FT4 and T4 assays have appropriate analytical performance to test pediatric patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 13, 2013

Siemens Healthcare Diagnostics, Inc.
c/o Matthew Gee
511 Benedict Ave.
TARRYTOWN NY 10591-5097

Re: K132249
Trade/Device Name: ADVIA Centaur® Ft4
ADVIA Centaur® T4
Regulation Number: 21 CFR 862.1695
Regulation Name: Free thyroxine test system
Regulatory Class: II
Product Code: CEC, KLI
Dated: August 9, 2013
Received: August 12, 2013

Dear Mr. Gee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k132249

Device Name: ADVIA Centaur® FT4
ADVIA Centaur® T4

Indications for Use:

For *in vitro* diagnostic use in the quantitative determination of free thyroxine (FT_4) in serum or plasma (heparinized or EDTA), using the ADVIA Centaur and ADVIA Centaur XP systems. Measurements of free thyroxine are used in the diagnosis and treatment of thyroid disease.

For *in vitro* diagnostic use in the quantitative determination of thyroxine (T_4) in serum using the ADVIA Centaur and ADVIA Centaur XP systems. Measurements of thyroxine are used in the diagnosis and treatment of thyroid disease.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k132249